

REMARKS

Claims 36-41 are pending in the present application. Claims 36, 38 and 39 were amended. No new matter was added by these amendments. Applicants respectfully request consideration of the present claims in view of the foregoing amendments and the following remarks. The Examiner objected to Claim 38 because of a misspelling. Applicants have amended Claim 38 to obviate the Examiner's objection.

Obviousness-Type Double Patenting Rejection

The Examiner rejected pending Claims 36-41, under the judicially created doctrine of obviousness-type double patenting, as unpatentable over the following U.S. patents:

- U.S. Patent No. 6,359,014 (hereinafter the '014 patent) – Claims 1, 2, 5, 6, 11 and 16;
- U.S. Patent No. 5,691,387 (hereinafter the '387 patent) – Claims 4, 7, 11 and 18;
- U.S. Patent No. RE 37,285 (hereinafter the '285 patent) – Claims 4, 7, 11 and 18;
- U.S. Patent No. 5,674,911 (hereinafter the '911 patent) – Claim 1.

The Examiner stated that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to compositions for treating patients, or to methods for treating patients, wherein the compositions have physical characteristics falling within the ranges recited in the instant claims.” The Examiner found that “the instant claims are broadly drawn to methods of preventing cell damage wherein the only active method step is the administration of a composition to a patient.” The Examiner concluded that “any patented claim that teaches administration of the recited composition to an animal, for whatever purpose, renders the instant claims obvious.” Applicants respectfully traverse this rejection for the following reasons.

Obviousness-type double patenting is a judicially created doctrine that may, in certain instances, prevent the owner of a pending application from using that application as a vehicle to obtain claims which vary from the owner's prior patent claims only in ways that are obvious in view of the prior art. See *In re Braithwaite*, 154 U.S.P.Q. 29, 34 (C.C.P.A. 1967). The test for

obviousness-type double patenting is whether the claimed invention in the subject application would have been obvious from the subject matter of the claims in the other case in light of the prior art. See *In re Longi*, 225 U.S.P.Q. 645, 648 (Fed. Cir. 1985). A patent containing an identical disclosure to the subject application, and co-pending with the subject application, can be used as a *basis* (“base patent”) for a double patenting rejection, but cannot be treated as “prior art.” See *In re White and Langer*, 160 U.S.P.Q. 417, 418 (C.C.P.A. 1969). Thus, a rejection founded on a conclusion that claims in an application differ from claims of a base “parent” patent only in an obvious manner, must be supported by citation of an additional reference that represents prior art relative to the application claims.

The ‘387 patent has been reissued as the ‘285 patent. Therefore the claims in the ‘387 patent are no longer in existence, and should not be used to support an obviousness-type double patenting rejection. Only the claims are compared in a rejection for double patenting. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 20 U.S.P.Q.2d 1392, 1394 (Fed. Cir. 1991). The present application derives internal priority from the ‘014 and ‘285 (reissue of ‘387) patents. These patents contained the same disclosure as the present application, and thus, clearly do not represent evidence of what was known to others “at the time the invention was made.” These patents were not available as references at the time the invention was made, and cannot be used as ‘prior art’ to support an obviousness-type double patenting rejection. No prior art has been provided to support an obviousness-type double patenting rejection based on the ‘014 and ‘285 patents. In this double patenting rejection, the Examiner relied solely on the language of the cited patent claims and supporting specification passages for each claim. In this case, neither the claim language nor the disclosure of a base patent, parent to the subject application, may be used to support the rejection. Thus, an obviousness-type double patenting rejection over the ‘014 and ‘285 patents has not been established.

An obviousness-type double patenting rejection can be maintained when the patent claims a species element and the subject application claims a broad genus. See *In re Goodman*, 29 U.S.P.Q.2d 2010, 2011, 2016 (Fed. Cir. 1993). A terminal disclaimer was voluntarily filed when the patent claims were directed to a genus and the claims of the subject application were

directed to a subgenus. See *Ortho Pharmaceutical Corp. v. Smith*, 22 U.S.P.Q.2d 1119, 1123 (Fed. Cir. 1992).

No genus/species relationship has been cited between the claims in the present application and the claims in the '014, and '285 patents. The claims in the present application are drawn to methods of preventing cell damage. Claims 4, 11 and 18 have been deleted in the '285 patent. The only existing claim in the '285 patent, among the cited claims, is Claim 7, drawn to a method of treating sickle cell anemia. The claims in the '014 are directed to methods of treating a patient with pathologic hydrophobic interactions in biological fluids. The claims in the patents at issue are all distinct, being drawn to different methods of treatment. Applicants respectfully maintain that Claims 36-41 of the present application are not rendered obvious by Claims 1, 2, 5, 6, 11, and 16 of the '014 patent, or by Claim 7 of the '285 patent.

In an obviousness-type double patenting rejection, there must be clear evidence to establish why the invention's variation in a second patent or application would have been obvious. See *In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986). In addition, double patenting is based on whether the claims of a patent and application are directed to different, independent and distinct inventions. Inventions are independent and distinct, although they relate to the same basic process and are capable of cojoint use. See *In re Sutherland*, 146 U.S.P.Q. 485, 491 (C.C.P.A. 1965).

The claims in the present application are directed to methods of preventing cell damage. Claim 1 in the '911 patent is directed to a method for treating an infection caused by a microorganism. The preamble of these respective claims clearly show that independent and distinct inventions are involved; these claims are directed to a different methods of treatment. The fact that similar compositions are capable of cojoint use, does not negate the fact that the inventions are independent and distinct. Patentable subject matter exists for novel methods of treatment using similar compositions. Applicants respectfully maintain that Claims 36-41 of the present application are not rendered obvious by Claim 1 of the '911 patent.

Therefore, for at least the above reasons Applicants respectfully maintain that Claims 36-41 are not obvious variants of the claims of the cited patents. Accordingly, Applicants respectfully request the withdrawal of this rejection.

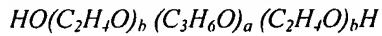
Rejection of Claims 36-41 under 35 U.S.C. §112, Second Paragraph

The Examiner rejected Claims 36-41 under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner asserted that Claims 36-41 were unclear as to the intended meaning of “substantially pure” and “non-pure.” The Examiner also asserted that these claims were indefinite because these method claims require the prevention of cell damage, but do not recite the step at which damage is prevented. Applicants respectfully traverse this rejection for the following reasons.

Applicants have amended Claims 36 and 38 to recite a mechanism for which cell damage is prevented, thus rendering moot the Examiner’s rejection regarding the recitation of a step at which cell damage is prevented. Support for these amendments are found on pages 6-9 and 16-17 of the specification.

Applicants respectfully maintain that the term “substantially pure” is defined in Claims 36 and 38, respectively, as follow:

... said substantially pure polyoxypolypropylene/polyoxyethylene block copolymer composition containing block copolymers with each of the block copolymers having the following general formula:



wherein a is an integer such that the molecular weight represented by the polyoxypolypropylene portion of the respective block copolymer is between 900 Daltons and 15,000 Daltons and b is an integer such that the molecular weight represented by the polyoxyethylene portion of the respective block copolymer constitutes between 5% and 95% of the respective block copolymer and the polydispersity value is less than approximately 1.07
....

Thus, a ‘substantially pure’ polyoxypolypropylene/polyoxyethylene block copolymer composition is a composition that contains polyoxypolypropylene/polyoxyethylene block copolymers defined by the recited chemical parameters. Applicants assert that the term “non-pure” is also inherently defined in Claims 36 and 38 as a polyoxypolypropylene/polyoxyethylene block copolymer composition that does not contain polyoxypolypropylene/polyoxyethylene block copolymers defined by the recited chemical parameters. Applicants also direct the Examiner’s attention to U.S. Patents 6,359,014 and 5,990,241, which stem from priority applications of the present

application. In these patents, the terms “substantially pure” and “non-pure” are also used in the patented claims, showing that these terms do not render claims indefinite. Applicants also direct the Examiner’s attention to pages 25, 36-38 and 42 of the specification which discusses the toxicity of the copolymers in terms of their polydispersity values and degree of unsaturation. It is known by those skilled in the art that a polydispersity value approaching one (ave M_w = ave M_n) would result from a polymer sample approaching homogeneous polymer sizes and molecular weights.

Therefore, for at least the above reasons, Applicants respectfully assert that Claims 36-41 are definite. Accordingly, Applicants request the withdrawal of this rejection.

Rejection of Claims 36, 38 and 40 under 35 U.S.C. §102(e)

The Examiner rejected Claims 36, 38 and 40 under 35 U.S.C. §102(e), as anticipated by U.S. Patent 5,674,911 to *Emanuele et al.* (the ‘911 patent). The Examiner asserted that the ‘911 patent teaches methods of treating infections by administering a POE/POP (polyoxyethylene/polyoxypropylene) block copolymer comprising a POE portion between 1,200 and 15,00[0] D, and wherein the POE portion represents 1-50% of the weight of the copolymer. The polydispersity of the copolymer may be 1.05. The Examiner also found that the copolymer in the ‘911 patent is less toxic than corresponding prior art compositions, and is substantially free of unsaturated molecules, and thus substantially pure. The Examiner concluded that the compound (copolymer) can be used to protect against damage to tissue cells by ameliorating infection. Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully assert that Claims 36 and 38 are each directed to a method for preventing cell damage, wherein the block copolymers prevent cell damage by restoring or maintaining non-adhesive cell surfaces. The ‘911 patent fails to teach or suggest a method for preventing cell damage, as claimed in the present application. Therefore, for at least these reasons, Applicants respectfully submit that Claims 36 and 38 are not anticipated by the ‘911 patent. Since Claims 37 and 39-41 recite additional claim features and independently depend from either Claim 36 or Claim 38, Applicants submit that these claims are not anticipated by the ‘911 patent. Accordingly, Applicants respectfully request the withdrawal of this rejection.

Rejection of Claims 36, 38 and 40 under 35 U.S.C. §102(f)

The Examiner rejected Claims 36, 38 and 40 under 35 U.S.C. §102(f), as anticipated by the '911 patent. The Examiner found that the '911 patent lists two inventors not listed on the present application, and that the present application lists two inventors not listed on the '911 patent. The Examiner concluded, based on his prior 102(e) rejection, that it was not clear who invented the present application. Applicants respectfully traverse this rejection for the following reasons.

Applicants respectfully assert that the '911 patent fails to disclose the claimed invention. As discussed above, Claims 36 and 38 are each directed to a method for preventing cell damage, wherein the block copolymers prevent cell damage by restoring or maintaining non-adhesive cell surfaces. The '911 patent teaches a method for treating infection, and fails to teach or suggest the claimed method. Therefore, for at least these reasons, Applicants respectfully submit that Claims 36 and 38 and dependent Claims 37 and 39-41 are patentable over the '911 patent. Accordingly, Applicants respectfully request the withdrawal of this rejection.

Patent Application No. 10/017,223

Title: Polyoxypropylene/Polyoxyethylene Copolymers with Improved Biological Activity

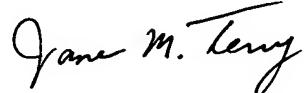
CONCLUSION

For at least the reasons given above, Applicants respectfully submit that Claims 36-41 define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

A check in the amount of \$465.00, the fee for a three-month extension of time, is enclosed. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855.

Applicants submit that the claims in the present application are in condition for allowance, and such action is courteously solicited. The Examiner is invited and encouraged to contact the undersigned attorney of record at telephone number listed below, if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,



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